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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,643	02/02/2001	Hirokazu Matsumoto	2523US0P	5991

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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 11/10/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,643	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 14-34 have been renumbered to 13-31 respectively.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group IA, claim(s) 1-3 and 7-8, drawn to a monoclonal antibody (P2L-1Ca) reactive with a C-terminal partial peptide of the 19P2 ligand.
- Group IB, claim(s) 1-3 and 7-8, drawn to a monoclonal antibody (P2L-2Ca) reactive with a C-terminal partial peptide of the 19P2 ligand.
    - These monoclonal antibodies are considered to be different inventive entities because they have different physical, chemical and binding characteristics.
- Group II-A, claim(s) 4-8, 21-24, drawn to a monoclonal antibody (P2L-1Ta) reactive with an intermediate partial peptide of the 19P2 ligand.
- Group II-B, claim(s) 4-8, 21-24, drawn to a monoclonal antibody (P2L-3Ta) reactive with an intermediate partial peptide of the 19P2 ligand.
- Group II-C, claim(s) 4-8, 21-24, drawn to a monoclonal antibody (P2L-1Ca) reactive with an intermediate partial peptide of the 19P2 ligand.
- Group II-D, claim(s) 4-8, 21-24, drawn to a monoclonal antibody (P2L-2Ca) reactive with an intermediate partial peptide of the 19P2 ligand.

- These monoclonal antibodies are considered to be different inventive entities because they have different physical, chemical and binding characteristics.

- Group III, claim(s) 9, drawn to a hybridoma.
  Species 1 monoclonal antibody reactive with C-terminal partial peptide of 19P2 ligand.
  Species 2 monoclonal antibody reactive with an intermediate partial peptide of 19P2 ligand.

- Group IV-A, claim(s) 10, 11, 14, 15 and 26-31 drawn to a monoclonal antibody (P2L-1Ta) that specifically binds to SEQ ID No. 11 and method for using the same.

- Group IV-B, claim(s) 10, 11, 14, 15 and 26-31 drawn to a monoclonal antibody (P2L-3Ta) that specifically binds to SEQ ID No. 11 and method for using the same.

- Group IV-C, claim(s) 10, 11, 14, 15 and 26-31 drawn to a monoclonal antibody (P2L-1Ca) that specifically binds to SEQ ID No. 11 and method for using the same.

- Group IV-D, claim(s) 10, 11, 14, 15 and 26-31 drawn to a monoclonal antibody (P2L-2Ca) that specifically binds to SEQ ID No. 11 and method for using the same.

  - These monoclonal antibodies are considered to be different inventive entities because they have different physical, chemical and binding characteristics.

- Group V-A, claim(s) 12, 13, 14, 16, 17 and 26-31, drawn to a monoclonal antibody (P2L-1Ta) that specifically binds to SEQ ID No. 7 and method for using the same.

- Group V-B, claim(s) 12, 13, 14, 16, 17 and 26-31, drawn to a monoclonal antibody (P2L-3Ta) that specifically binds to SEQ ID No. 7 and method for using the same.

- Group V-C, claim(s) 12, 13, 14, 16, 17 and 26-31, drawn to a monoclonal antibody (P2L-1Ca) that specifically binds to SEQ ID No. 7 and method for using the same.

- Group V-D, claim(s) 12, 13, 14, 16, 17 and 26-31, drawn to a monoclonal antibody (P2L-2Ca) that specifically binds to SEQ ID No. 7 and method for using the same.

  - These monoclonal antibodies are considered to be different inventive entities because they have different physical, chemical and binding characteristics.

- Group VI-A, claim(s) 18, drawn to a monoclonal antibody that specifically binds with SEQ ID No. 1.

- Group VI-B, claim(s) 18, drawn to a monoclonal antibody that specifically binds with SEQ ID No. 2.

- Group VI-C, claim(s) 18, drawn to a monoclonal antibody that specifically binds with SEQ ID No. 3.

- Group VI-D, claim(s) 18, drawn to a monoclonal antibody that specifically binds with SEQ ID No. 5.

- Group VI-E, claim(s) 18, drawn to a monoclonal antibody that specifically binds with SEQ ID No. 12.

    - These monoclonal antibodies are considered to be different inventive entities because they have different physical, chemical and binding characteristics.

- Group VII-A, claim(s) 19, drawn to a monoclonal antibody that specifically binds with amino acid residues 12 to 24 of SEQ ID No. 1.

- Group VII-B, claim(s) 19, drawn to a monoclonal antibody that specifically binds with amino acid residues 12 to 24 of SEQ ID No. 2.

- Group VII-C, claim(s) 19, drawn to a monoclonal antibody that specifically binds with amino acid residues 12 to 24 of SEQ ID No. 3.

    - These monoclonal antibodies are considered to be different inventive entities because they have different physical, chemical and binding characteristics.

- Group VIII, claim(s) 20, drawn to a monoclonal antibody that specifically binds with 19P2 ligand peptide but does not bind with SEQ ID No. 4 or 6.

- Group IX-A, claim(s) 25, drawn to an isolated hybridoma cell line producing P2L-1Ta.

- Group IX-B, claim(s) 25, drawn to an isolated hybridoma cell line producing P2L-3Ta.

- Group IX-C, claim(s) 25, drawn to an isolated hybridoma cell line producing P2L-1Ca.

- Group IX-D, claim(s) 25, drawn to an isolated hybridoma cell line producing P2L-2Ca.
    - These monoclonal antibodies are considered to be different inventive entities because they have different physical, chemical and binding characteristics.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: multiple monoclonal antibodies, hybridomas and methods of using them are claimed. The monoclonal antibodies are different because they have different physical characteristics such as structure and sequence as well as different binding characteristics. They are also recited as binding to different sequences.

4. The inventions listed in Groups I-A and I-B, and II-A through II-D, for example, are restricted as such because each of these monoclonal antibodies are considered to be a different inventive entity and are not linked. In Group I, for example, multiple inventions are being claimed in the same claim, therefore, the claims have been restricted into different Groups as explained above.

5. The inventions listed as Groups I – IX do not have a single technical feature. Even though some of the monoclonal antibodies are recited as specifically binding to a partial peptide of the 19P2 ligand, the peptide is not, per se, a feature of the claimed inventions.

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

7. The species are listed above.

8. Applicant is required, in reply to this action, to elect a single group and a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently

added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of monoclonal antibody are patentably distinct because they have different physical, chemical and binding characteristics.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday and Thursday from 9:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

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